



# 129th MAINE LEGISLATURE

## FIRST REGULAR SESSION-2019

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Legislative Document

No. 1616

H.P. 1168

House of Representatives, April 23, 2019

### An Act To Establish the Vaccine Consumer Protection Program

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Reference to the Committee on Health and Human Services suggested and ordered printed.

A handwritten signature in cursive script that reads "Robert B. Hunt".

ROBERT B. HUNT  
Clerk

Presented by Representative O'CONNOR of Berwick.

Cosponsored by Senator FOLEY of York and

Representatives: COREY of Windham, GRIFFIN of Levant, JAVNER of Chester, ORDWAY of Standish, SAMPSON of Alfred, WADSWORTH of Hiram, Senator: MIRAMANT of Knox.

1 **Be it enacted by the People of the State of Maine as follows:**

2 **Sec. 1. 22 MRSA c. 251, sub-c. 2-B** is enacted to read:

3 **SUBCHAPTER 2-B**

4 **VACCINE CONSUMER PROTECTION**

5 **§1071. Vaccine Consumer Protection Program**

6 **1. Definitions.** As used in this subchapter, unless the context otherwise indicates,  
7 the following terms have the following meanings.

8 A. "Federal Vaccine Adverse Events Reporting System" means a national vaccine  
9 safety surveillance program cosponsored by the United States Department of Health  
10 and Human Services, Food and Drug Administration and Centers for Disease Control  
11 and Prevention.

12 B. "Health care provider" means a physician, nurse, clinic, hospital or other entity  
13 licensed by the State to provide health care services that administers vaccines.

14 C. "National Vaccine Injury Compensation Program" means the National Vaccine  
15 Injury Compensation Program established by 42 United States Code, Section 300aa-  
16 10.

17 D. "Office" means the Vaccine Consumer Protection Office established in subsection  
18 2.

19 E. "Ombudsman" means the vaccine injury ombudsman appointed pursuant to  
20 subsection 2.

21 F. "Program" means the Vaccine Consumer Protection Program established in  
22 subsection 2.

23 G. "Vaccine" has the same meaning as "immunizing agent" as defined in section  
24 1061, subsection 2.

25 **2. Program established.** The Vaccine Consumer Protection Program is established  
26 within the department. The program may not be administered as part of the same  
27 administrative unit as the Universal Childhood Immunization Program established under  
28 section 1066. The Vaccine Consumer Protection Office is established within the  
29 department to carry out the purposes of the program. The commissioner shall appoint a  
30 vaccine injury ombudsman to assist members of the public who suspect vaccine injury.

31 **3. Vaccine Injury Board.** The commissioner shall establish the Vaccine Injury  
32 Board to advise the office in providing services under this section. The board must be  
33 composed of health care providers and vaccine injury victims or parents or legal  
34 guardians of victims who are minors. At least 1/2 of the members of the board must be  
35 vaccine injury victims or victims' parents or legal guardians.

36 **4. Services.** Under the program, the office shall:

1 A. Provide information to the public regarding assessment, diagnosis and treatment  
2 of potential vaccine injuries by a physician trained and qualified in vaccine injury  
3 assessment, diagnosis and treatment, according to an established standard of care, and  
4 refer all members of the public reporting suspected vaccine adverse events to such a  
5 qualified physician;

6 B. Take actions necessary to ensure that at least one physician per congressional  
7 district, who is trained and qualified in vaccine injury assessment, diagnosis and  
8 treatment, agrees to be available, as part of the physician's medical duties, to offer  
9 expert witness testimony on behalf of vaccine injury victims in proceedings under the  
10 United States Department of Health and Human Services, National Vaccine Injury  
11 Compensation Program or civil vaccine injury proceedings;

12 C. Ensure that health care providers respond to all potential vaccine injury cases  
13 brought to the health care providers' attention by reporting the cases to the federal  
14 Vaccine Adverse Events Reporting System and referring potential injury victims to  
15 the ombudsman for assistance in obtaining evaluations and care;

16 D. Establish treatment guidelines and ethical standards for health care providers  
17 administering vaccines or caring for vaccinated populations based on information  
18 provided by the United States Department of Health and Human Services, Centers for  
19 Disease Control and Prevention and National Vaccine Injury Compensation Program,  
20 vaccine manufacturer package inserts and current research;

21 E. Every 3 years, provide continuing medical education and vaccine safety and  
22 efficacy training for all health care providers based on information provided by the  
23 United States Department of Health and Human Services, Centers for Disease  
24 Control and Prevention, and National Vaccine Injury Compensation Program,  
25 vaccine manufacturer package inserts and current research;

26 F. At least twice per year, provide a public forum on vaccine adverse events that  
27 includes participants who are vaccine injury victims on at least half of the panels at  
28 the forum;

29 G. Establish and maintain a state vaccine information sheet that includes the  
30 following disclosures and consent.

31 (1) Before administering a vaccine to a patient, a health care provider shall  
32 provide to the patient or to the patient's parent or legal guardian if the patient is a  
33 minor a federal vaccine information sheet developed by the United States  
34 Department of Health and Human Services, Centers for Disease Control and  
35 Prevention in accordance with 42 United States Code, Section 300aa-26 and the  
36 following information via the state vaccine information sheet:

37 (a) That the patient or the patient's parent or legal guardian if the patient is a  
38 minor may decline some or all vaccines;

39 (b) That the health care provider administering the vaccine is liable for harm  
40 to the patient caused by the vaccine or its administration if the provider does  
41 not follow manufacturer contraindications listed on the vaccine manufacturer  
42 package insert;

1 (c) That the vaccine manufacturer is not liable for harm to the patient or the  
2 death of the patient caused by the vaccine, even if the harm or death was  
3 caused by the manufacturer's negligence in the design of the vaccine;

4 (d) If a health care provider is administering more than one vaccine in a  
5 single visit and, if applicable, that no safety studies have been performed,  
6 before or after approval of the vaccine, on the combination of vaccines the  
7 provider plans to administer;

8 (e) Information for each vaccine being administered;

9 (f) If a health care provider plans to administer a vaccine containing  
10 mercury, that an alternative vaccine is available that is mercury-free; and

11 (g) That medical and religious exemptions are available pursuant to sections  
12 1079 and 1080 to individuals who choose not to receive a vaccine that a  
13 school or employer requires.

14 (2) After providing the disclosures required in subparagraph (1) and before  
15 administering a vaccine to a patient, a health care provider shall obtain written,  
16 informed consent for each vaccine from the patient or the patient's parent or legal  
17 guardian if the patient is a minor; and

18 H. Notwithstanding any other provision of law to the contrary, establish mandatory  
19 guidelines for vaccine administration for health care providers and a complaint and  
20 censure process under which a member of the public may bring a complaint against a  
21 health care provider when the health care provider:

22 (1) Vaccinates outside guidelines contained in vaccine manufacturer package  
23 inserts or guidelines established by the program or the United States Department  
24 of Health and Human Services, Health Resources and Services Administration  
25 and Centers for Disease Control and Prevention;

26 (2) Before vaccine administration, fails to provide a document describing  
27 potential contraindications and adverse events to the patient or the patient's parent  
28 or legal guardian if the patient is a minor;

29 (3) Before vaccine administration, fails to provide the state vaccine information  
30 sheet and a federal vaccine information sheet to the patient or the patient's parent  
31 or legal guardian if the patient is a minor;

32 (4) Before vaccine administration, fails to acquire written informed consent for  
33 vaccination from the patient or the patient's parent or legal guardian if the patient  
34 is a minor;

35 (5) Fails to report a patient-reported vaccine adverse event or suspected vaccine  
36 injury to the federal Vaccine Adverse Events Reporting System;

37 (6) Fails to refer to the office a patient who has reported a vaccine adverse event  
38 or the parent or legal guardian of the patient if the patient is a minor;

39 (7) Engages in coercive practices as defined by program guidelines;

40 (8) Makes public or private vaccine safety and efficacy claims, outside of  
41 personal belief claims, to the public or patients that are unsupported by

1 information from the United States Department of Health and Human Services,  
2 Health Resources and Services Administration and Centers for Disease Control  
3 and Prevention, vaccine manufacturer package inserts or published research, such  
4 as the claim that vaccines are safe;

5 (9) Engages in the harassment of patients, parents, legal guardians or members  
6 of the public for the vaccine choices of those individuals; or

7 (10) Vaccinates a child under the age of 18 without the written informed consent  
8 for each vaccine being administered from the child's parent or legal guardian, or  
9 outside the physical presence and supervision of the child's parent or legal  
10 guardian.

11 **§1072. Health care provider's rights**

12 The department may not coerce a health care provider to administer a vaccine or  
13 subject a health care provider to punitive action for:

14 **1. Medical exemptions.** Providing a medical exemption for a vaccine;

15 **2. Decline to administer.** Declining to administer a vaccine;

16 **3. Decline to recommend.** Declining to recommend a vaccine be administered;

17 **4. State and federal childhood immunization programs.** Choosing not to  
18 participate in the Universal Childhood Immunization Program established under section  
19 1066 or a federal childhood immunization program; or

20 **5. Advocate.** Advocating for potential vaccine injury cases or acting as an expert  
21 witness for vaccine injury victims.

22 **§1073. Patient right of refusal**

23 A patient or the patient's parent or legal guardian if the patient is a minor has the right  
24 to refuse a vaccine, and any such refusal may not be taken into consideration in a child  
25 protective services complaint. Vaccine administration may not be required for  
26 reunification in a child protective services case. The Office of Child and Family Services  
27 may not authorize or facilitate the administration of any vaccine to a child in its custody  
28 without written parental consent.

29 **§1074. Vaccine death investigations**

30 Upon the request of the next of kin of the deceased person, the office shall investigate  
31 a death that is suspected to have been caused by the administration of a vaccine. The  
32 office shall provide the next of kin a detailed report regarding the investigation.

33 **§1075. Incentive prohibition**

34 A state agency may not approve a financial or other incentive that encourages the  
35 increased use of vaccines, including, but not limited to, higher reimbursement rates to  
36 health care providers based on patient vaccination rates, awards to health care providers

1 for increased vaccination rates of patients, payments or rewards to patients for receiving a  
2 vaccine or any other incentive that may encourage the increased use of a vaccine based  
3 on a consideration other than the best interests of the individual receiving the vaccine.

4 **§1076. Vaccine prescriptions**

5 Notwithstanding any other provision of law to the contrary, a person who is not a  
6 health care provider may not administer a vaccine without a prescription from a health  
7 care provider.

8 **§1077. Standing orders**

9 Notwithstanding any other provision of law, a vaccine may not be prescribed by  
10 standing order.

11 **§1078. Annual report**

12 The office shall provide an annual report to the United States Department of Health  
13 and Human Services, Centers for Disease Control and Prevention, Immunization Safety  
14 Office on the number of vaccine adverse event reports, assessments and diagnosed cases  
15 of vaccine injury and death in the State.

16 **§1079. Religious exemptions**

17 Notwithstanding any other provision of law to the contrary, a person or the person's  
18 parent or legal guardian if the person is a minor has the right to refuse a vaccine based on  
19 a sincere religious belief that is contrary to a vaccination requirement without coercion,  
20 consequence or retaliation.

21 **§1080. Medical exemptions**

22 Notwithstanding any other provision of law to the contrary, the department or any  
23 other state agency may not limit the application of any law that allows a health care  
24 provider to provide a medical exemption if the health care provider determines that  
25 administration of a vaccine is medically inadvisable for a patient, and a patient has the  
26 right to refuse a vaccine without coercion, consequence or retaliation.

27 **§1081. Administration of certain vaccines prohibited**

28 A person may administer a vaccine only if:

29 **1. Vaccine safety.** The study relied on by the United States Department of Health  
30 and Human Services, Food and Drug Administration for approval of the vaccine  
31 evaluated the safety of the vaccine:

32 A. Against a control group that received an inert, saline placebo; and

33 B. For a sufficient time to identify potential autoimmune, neurological or chronic  
34 health conditions that may arise on or after the first anniversary of the date the  
35 vaccine is administered;

36 **2. Evaluation.** The vaccine has been evaluated for the vaccine's potential to:

